

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,

Plaintiff,

V.

SAREPTA THERAPEUTICS, INC.,

Defendant.

SAREPTA THERAPEUTICS, INC. and THE
UNIVERSITY OF WESTERN AUSTRALIA,

Defendant/Counter-Plaintiffs,

V.

NIPPON SHINYAKU CO., LTD.
and NS PHARMA, INC.

Plaintiff/Counter-Defendants.

C.A. No. 21-1015 (GBW)

PUBLIC VERSION

Confidential Version Filed: August 3, 2023
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**LETTER TO THE HONORABLE GREGORY B. WILLIAMS REGARDING
MOTION TO EXCLUDE DR. MATTHEW WOOD AS AN EXPERT WITNESS**

Dear Judge Williams:

Nippon Shinyaku (“NS”) has retained Dr. Matthew Wood to serve as an expert witness in this case. [REDACTED]

[REDACTED] During their relationship, Sarepta engaged Dr. Wood as a consulting and testifying expert in interference proceedings before the U.S. Patent and Trademark Office (“USPTO”), where Dr. Wood worked closely with Sarepta’s counsel on patents directed to exon skipping for treatment of Duchenne Muscular Dystrophy (“DMD”) in the same patent family as those in suit here. Sarepta also engaged Dr. Wood as a consultant [REDACTED]

[REDACTED] During these engagements, Sarepta shared both confidential technical information and privileged information with Dr. Wood, and Sarepta would be greatly prejudiced should that information be disclosed to NS. The only adequate remedy to protect Sarepta from harm based on this conflict of interest is to disqualify Dr. Wood from serving as an expert for NS. Accordingly, Defendants respectfully request that the Court disqualify Dr. Wood from serving as an expert for NS in this case.

I. FACTUAL BACKGROUND

[REDACTED]

In 2014, Sarepta retained Dr. Wood as an expert in connection with three interference proceedings before the USPTO (the “Interferences”) involving patents directed to ASOs for treating DMD.² Those patents (i) name the same inventors, (ii) claim priority to the same parent application, (iii) have the same effective filing date, and (iv) contain substantially the same text, figures, and data as the patents licensed to Sarepta that are at issue in this litigation. *Compare* D.I. 195-1 at Exs. A-C with Exs. 2-5. [REDACTED]

¹ “Evans Decl.” refers to the accompanying Declaration of Marc D. Evans.

² [REDACTED]

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In his capacity as an expert witness in the Interferences, Dr. Wood worked closely with Sarepta's in-house and outside counsel, including several of the same Finnegan attorneys representing Sarepta in this litigation. Dr. Wood also worked closely with Sarepta's counsel to prepare expert declarations and to prepare for two depositions in those proceedings. Evans Decl., ¶ 17.³

[REDACTED]

Notably, in this litigation, NS contends that Van Ommen et al., WO 2004/083432 A1 ("VO") renders the asserted claims of the UWA patents obvious. Exs. 9-10. Dr. Wood provided opinions in the Interferences as to why VO did *not* render obvious the claims of the related patents at issue. Ex. 11. Given that it is relying on the same reference that was at issue in the Interferences and that was the subject of extensive analysis by Dr. Wood there, NS cannot contend that the information obtained by Dr. Wood in connection with his work in the Interferences is not relevant to this case, whether for obviousness or other patent issues. Indeed, NS has indicated that it intends to rely in this case on statements made in the Interferences. Ex. 12. After the Interferences concluded, Sarepta—through counsel—sought Dr. Wood's assistance yet again [REDACTED]. In connection with those proceedings, Dr. Wood met regularly—[REDACTED]—with Sarepta's [REDACTED] counsel. As reflected in contemporaneous communications from Dr. Wood to Sarepta, those meetings included confidential discussions [REDACTED].

[REDACTED]

II. ARGUMENT

This Court has broad inherent authority to disqualify expert witnesses to preserve public confidence in the fairness and integrity of the judicial system, such as conflicts of interest, and to protect breaches of privileges from an expert switching sides. *See Merck Sharp & Dohme Corp. v. Teva Pharms. USA, Inc.*, No. 14-874-SLR/SRF, 2015 WL 5163035, at *2 (D. Del. Sept. 3, 2015). When presented with an objection to an expert, a court must determine (1) whether it was objectively reasonable for the moving party to believe that it had a confidential relationship with the expert; and (2) whether the moving party disclosed confidential information to the expert relevant to the current litigation. *Id.* Courts also consider a third factor, public interest, in evaluating whether an expert can testify. *Id.* Each of those factors favors Sarepta here.

[REDACTED] And Dr. Wood indisputably received confidential

³ Numerous documents reflecting Dr. Wood's involvement in the Interferences are protected by the attorney-client privilege and/or the work product immunity. Sarepta is prepared to make those documents—and any of the other documents cited in the Evans Declaration—available for *in camera* review should the Court so request.

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technical and legal information from Sarepta relevant to this litigation. Courts afford special protection to such confidential information in light of the real and serious threat of economic injury attendant with disclosure of scientific information. *See Safe Flight Instrument Corp. v. Sundstrand Data Control Inc.*, 682 F. Supp. 20, 22 (D. Del. 1988); *see also Lifewatch Serv. Inc. v. Braemer Inc.*, No. 09 C 6001, 2010 WL 3909483, at *2 (N.D. Ill. Sept. 28, 2010) (“[C]ourts have disqualified experts in patent infringement cases where the expert has gained confidential information concerning the patent or technology at issue in the litigation.”).

_____ the information the expert obtained is relevant to the instant litigation, and there is a risk of adverse use or disclosure. *See Merck*, 2015 WL 5163035, at *3; *see also Auto-Kaps, LLC v. Clorox Co.*, No. 15 Civ. 1737, 2016 WL 1122037, at *4 (E.D.N.Y. Mar. 22, 2016) (“An expert cannot build [an ethical] wall in his own mind, despite his best efforts to do so.”). Even if NS contends that Dr. Wood will somehow opine without exposure to confidential information, Sarepta cannot ensure that the privileged information it previously gave him will remain secure—and neither can Dr. Wood.

The risk of prejudice to Sarepta outweighs any prejudice to NS. NS has not demonstrated that it cannot find another qualified expert, instead choosing to retain an expert Sarepta has engaged for years to consult on similar issues.⁴ Evans Decl. ¶ 28. Furthermore, NS would not be substantially harmed by the exclusion of Dr. Wood, because NS had actual knowledge of Dr. Wood’s relationship with Sarepta before seeking to engage him. *See Rhodes v. E.I. Du Pont de Nemours and Co.*, 558 F. Supp. 2d 660, 671 (S.D. W. Va. 2008) (defendant was aware of prior connection between plaintiffs and expert, which weighed in favor of fairness of disqualifying expert). Indeed, counsel for NS expressly stated during a June 2, 2023 meet and confer that NS retained Dr. Wood precisely *because* he was previously Sarepta’s expert witness in USPTO proceedings relating to exon 53-skipping oligonucleotides.

Finally, notwithstanding _____ Sarepta’s disclosure to him of relevant, confidential information, notions of fundamental fairness require precluding Dr. Wood from “switching sides” and serving as an expert for NS. Dr. Wood served as an expert for Sarepta during the Interferences _____ with respect to issues of validity of patents in the same family as the patents at issue here. NS now wants Dr. Wood to switch sides and take a position directly adverse to Defendants. This includes, by example, taking the exact opposite position relating to the VO reference, as set forth above. This is a clear-cut instance of “switching sides,” which courts have held sully the public trust in the justice system and justify a bright-line rule of disqualification. *See Koch Refining Co. v. Jennifer L. Boudreau MV*, 85 F.3d 1178, 1181 (5th Cir. 1996).

III. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court disqualify Dr. Wood from serving as an expert for NS.

⁴ For example, NS has already served a declaration from Dr. Nathan Luedtke, another expert on ASOs, during claim construction, and provided Sarepta notice of five other experts.

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Respectfully,

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

MED/bac

cc: Clerk of the Court (via hand delivery)
All Counsel of Record (via electronic mail)